copayment amount [41.2% with an increase in generic copayment amount; 74.5% with an increased in preferred brand copayment amount; 68.5% with an increase in non-preferred brand copayment amount]. **CONCLUSIONS:** 12% of continuously enroll beneficiaries experienced benefit design changes that could impact prescription utilization and adherence measures. Most of them experienced an increased in copayment amount, especially for brand name formulary drugs. Benefit design should be incorporated into prescription utilization and adherence studies to more accurately estimate these measures.

PHP94
ASSESSING LEVELS OF THERAPEUTIC IMPROVEMENT: AN INTERNATIONAL COMPARISON
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OBJECTIVES: Several jurisdictions assess the relative clinical effectiveness of new therapeutic agents compared to existing products and assign rankings of therapeutic improvement. These rankings influence and sometimes determine the potential pricing of the product in the respective jurisdiction. This study sought to compare the level of therapeutic improvement assessments in three jurisdictions and discuss the parameters leading to any differences observed in level of therapeutic improvement rankings. **METHODS:** Efforts were taken to standardize the level of therapeutic ranking systems of Canada, France and Germany to have comparable levels of therapeutic improvement. We identified 128 unique substances reviewed by Canada's Patented Medicines Price Review Board (PMPRB) between 2011 and 2013 for which level of therapeutic improvement rankings were assigned. Of these, 18 were also reviewed by the *Haute-Autorité de Santé (HAS)* in France and the Federal Joint Committee (*GB-A*) in Germany. The level of therapeutic improvement rankings were observed in each jurisdiction to assess concurrence among the organizations. **RESULTS:** Preliminary results indicated that there was concurrence in the level of therapeutic improvement rankings across the jurisdictions with most products receiving low levels of therapeutic improvement (n=13). **CONCLUSIONS:** Overall, concurrence was observed among the agencies' level of therapeutic improvement rankings for the 18 drugs commonly evaluated. Elements such as a review's timing and order, the primary indication and relevant comparators identified in the therapeutic area by each jurisdiction are important to understand discrepancies in level of therapeutic improvement suggested. Discussion surrounding limitations of standardization is necessary to inform results.

PHP95
FACTORS INFLUENCING UNITED STATES PAYER COVERAGE OF ELECTIVE BIOMARKER DIAGNOSTICS
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OBJECTIVES: The adoption of elective biomarker tests within US health plans has been slow. Without standardized guidelines, payers vary in their coverage policies of elective biomarker diagnostics. The aim of this study was to identify factors, including the positive predictive value (PPV) of a test, that influence current coverage and reimbursement practices of elective biomarker tests amongst US payers. **METHODS:** Independent assessments were conducted with two groups of US payers comprised of both medical and pharmacy directors from national and regional health plans. In October 2013, a focus group of 44 US payers used 7-point Likert scales to evaluate hypothetical scenarios involving varying PPVs. In December 2013, 60 US payers were surveyed using 7-point Likert scales to categorize factors that influence the coverage of elective biomarker diagnostics within their health plans. Elective biomarkers were defined as diagnostic tests that are not required as part of the FDA-approved labeling, but may be used in conjunction since evidence demonstrates that test results may determine treatment choices and/or outcomes. Chi-squared analyses are in progress to observe differences in responses between the two independent payer groups, medical and pharmacy directors, as well as national and regional health plans. **RESULTS:** Based on focus group results, 6 (13.6%), 13 (29.5%), 31 (70.5%), and 40 (90.1%) US payers were more likely to cover biomarker tests as PPV increased from 20%, 40%, 60% and 80%, respectively. 52 (86.6%) surveyed payers rated the ability to predict the effectiveness of a particular therapy, and 42 (70.0%) rated the ability to reduce the frequency of other clinical tests as the main factors influencing coverage decisions. **CONCLUSIONS:** In lieu of standardized guidelines, this research indicates that the more accurate and effective the biomarker test is at determining treatment choices and/or outcomes, the more likely it will be covered by US health plans.

PHP96
NATURE OF ENDPOINTS IN MARKET ACCESS AGREEMENTS
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OBJECTIVES: Payers are strongly reluctant to value surrogate endpoints (SEP) as they carry substantial uncertainty on the final endpoint. However, it seems that SEP are common in payment for performance (P4P) agreements. The objective of this project was to Identify the proportion of SEP used in P4P and coverage with evidence development (CED). **METHODS:** Market access agreements (MAA) were identified from literature review, completed agencies websites, and experts input. P4P and CED were selected. Performance endpoints were classified as SEP or hard endpoint (HEP). **RESULTS:** 149 MAA were identified in 13 countries (France, UK, Italy, Sweden, Lithuania, Serbia, Slovenia, Germany, Denmark, Portugal, US, Australia, Canada). 39% were P4P (individual outcome-based), and 29% were CED (collective outcome-based) agreements. The majority of CED endpoints were HEP (92%), such as overall survival, decrease in hospitalizations/ prescriptions, delay switch to insulin treatment, real world data collection (e.g. long term safety and efficacy, drug conditions of use in practice). In contrast, the majority of P4P were SEP (89%), such as assessment of short term effectiveness, targeting a short term laboratory value (e.g. decrease in total cholesterol levels, HbA1c, etc.). All oncology drugs P4P had SEP performance criteria. There were few P4P (14%) with HEP (e.g. fracture, graft rejection for transplant), and few CEDs (8%) for which there were SEP (e.g. monitoring of HbA1c for antidiabetics in Italy). **CONCLUSIONS:** Although SEP are considered as not reliable from payers' perspective to fund newly approved products, they have become widely acceptable for defining success criteria in P4P. This highlights the limitation of P4P, and more research would be needed to assess the actual predictive value of such endpoints. On the opposite, CED appears to be an appropriate tool to address payers' uncertainty as they rely on HEP for decision making.

PHP97
CHALLENGES FACED BY DECISION MAKERS FROM MIDDLE INCOME COUNTRIES IN TRANSFERRING PHARMACOECONOMIC DATA AND ANALYSES FROM OTHER JURISDICTIONS
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OBJECTIVES: Decision makers in middle income countries are using pharmacoeconomics studies (PEs) and health technology assessments (HTAs) in pricing and reimbursement decisions. However, whilst many of these jurisdictions have local submission guidelines and local expertise, the studies themselves often use models developed elsewhere and elements of data from countries other than the jurisdiction concerned. The objectives of this study were to assess the challenges faced by decision makers in transferring pharmacoeconomic data and analyses from other jurisdictions. **METHODS:** We conducted an interview survey of representatives of decision making bodies from jurisdictions in Asia, Central and Eastern Europe, and Latin America that had at least one year's experience of using PEs and HTAs. **RESULTS:** Representatives of the relevant organizations in 12 countries were interviewed. All 12 jurisdictions had developed official guidelines for the conduct of HTAs or PEs. All but one of the organizations evaluated studies submitted to them, but 9 also conducted studies and 7 commissioned them. Nine of the organizations stated that, in evaluating HTAs or PEs submitted to them, they had consulted a study performed in a different jurisdiction. Data on relevant treatment effect was generally considered more transferable than those on prices/unit costs. Views on the transferability of epidemiological data, data on resource use and health state preference values were more mixed. Eight of the respondents stated that analyses submitted to them had used models developed in other jurisdictions. Four of the organizations had a policy requiring models to be adapted to reflect local circumstances. **CONCLUSIONS:** Decision makers in middle income countries were facing several challenges in transferring data or studies, mainly due to differences in current standard of care, practice patterns or GDP between the developed countries where the majority of the studies are conducted and their own jurisdiction.

HEALTH CARE USE & POLICY STUDIES – Health Care Research & Education

PHP98
SHORTCUTTING DRUG DEVELOPMENT: ECONOMIC BENEFITS OF USING GENOME-WIDE ASSOCIATION STUDIES (GWAS) TO REPOSITION EXISTING DRUGS TO OTHER THERAPEUTIC AREAS
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BACKGROUND: GWAS can identify targets of marketed drugs that are strongly associated with disease(s) different from approved indication, providing opportunities to substantially shorten the drug development process by repositioning the drug as treatment for the newly identified disease, potentially yielding substantial socioeconomic benefits. **OBJECTIVES:** To estimate economic benefits of repositioning three drugs to GWAS-identified diseases **METHODS:** GWAS were used to identify denosumab (currently for osteoporosis) as possible treatment for Crohn's disease, melatonin (circadian adjustment) for diabetes, and niacin (lipid-lowering) for aortic stenosis (AS). Economic models were constructed for the three illnesses--using data from Canadian registries, claims databases and clinical trials--comparing current management of the target illness with use of the repositioned drug. Costs (2013 CAD) were obtained from Medicare, Ontario Case Costing Project and price lists. Analyses covered each province and Canada. **RESULTS:** In all three cases, the repositioned product was dominant over current treatment mix, even at relatively low levels of uptake (>5%). With 50% uptake, in Crohn's, denosumab would provide substantial reductions in side-effects and savings of $1,619/pt, resulting in $161 million in annual savings across Canada; in diabetes, melatonin would save $205/pt annually, or more than $365 million for Canada, assuming equal efficacy; in AS, niacin would save $4.5 million in Quebec alone, largely by averting valve replacement surgery, providing additional benefits via reduced associated morbidity and mortality. Extensive sensitivity analyses showed these results to remain directionally the same except at extremely low rates of uptake or with significant increases in the price of the repositioned product. **CONCLUSIONS:** Using GWAS data to reposition existing drugs to other diseases offers sizeable reductions in the cost and time of drug development and would provide considerable economic benefits to the health care system. Additional efforts should be made to pursue this attractive path to effective "novel" treatments

PHP99
EXPLORING AWARENESS AMONG GENERAL PUBLIC TOWARDS ISSUES RELATED TO MEDICATION SAFETY IN QUETTA, PAKISTAN
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OBJECTIVES: The study aims to assess general public awareness towards issues related to medication safety in Quetta City, Pakistan. **METHODS:** A cross-sectional

study was conducted among general public in Quetta, Pakistan by using a convenient sampling technique. A total of one thousand respondents were approached and 927 consumers participated in the survey giving a response rate of 92.7%. Data was analyzed by using SPSS version 18.0 and descriptive statistics were reported where appropriate. **RESULTS:** Majority of the respondents (n=609, 65.7%) were not aware of possible side effects of their current medications. A total of 144 respondents (15.5%) believed that all medicines registered in Pakistan are safe to use and they do not have any side effects. About 44.4% (n=412) of the respondents claimed that they share their unused medicines with family and friends who are having similar illness. Majority of respondents 87.7% (n=813) were not satisfied with the drug information provided by the health care professionals. The present study also found that more than 80% of the respondents (n=742) did report that they never read the labels of their medication before using. **CONCLUSIONS:** The present study revealed poor level of public knowledge regarding medication safety. It is evident that public underestimates the risk of their medications. There is a general lack of awareness and understanding among the public especially towards side effects.

PHP100

CONTRIBUTION OF HEALTH ECONOMICS & OUTCOMES RESEARCH STUDIES OF COLOMBIA TO ISPOR CONFERENCES

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OBJECTIVES: The aim of this analysis was to summarize the contribution of Colombian papers to ISPOR conferences from 1998 to 2013. **METHODS:** It was developed a review of ISPOR Scientific Presentations Database from 1998 to 2013, filtering by abstract, by the word "Colombia" for each ISPOR meeting (International, European, Asian, and Latin American), we obtained a list of all abstracts those ones without Colombian authors were excluded. Abstracts were classified by disease, topic, and topic subcategory taking into account the register of each one. It was taken into account if authors or abstract relate any support of pharmaceutical or/and devices industry. Descriptive statistics were applied by disease and study type. **RESULTS:** A total of 258 abstracts were identified, 25 were excluded because they have no Colombian authors; 233 abstracts were included in the analysis, 111 from International (47.6%), 12 from European (5.2%), 1 from Asia-Pacific (0.4%) and 109 from Latin America Conference (46.8%). Over time, cumulative numbers of abstracts are increasing exponentially. The majority of abstracts were costs studies (76.4%), followed by Health Care Use & Policy Studies (13.3%), Clinical Outcomes Studies (6.0%), and others (10, 4.3%). The three most frequent diseases were cancer (12.4%), vaccine (12.0%) and infections (10.3%). The three most frequent cost studies developed were classified as cost-effectiveness analysis (61.8%), Cost of Illness studies (10.7%) and budget impact analysis (9.0%); Of included studies, 51.9% contain any author related with pharmaceutical or/and devices industry. There may be underreporting of studies due the filter was applied only for abstract content, neither by title nor authors; underreport on Scientific Presentations Database; and underreporting of pharmaceutical industries support due it is not disclosed on abstract. **CONCLUSIONS:** The contribution of Colombia to ISPOR Conferences have been increasing markedly, going from 1 paper presented in 2004 to 93 papers presented in 2013

HEALTH CARE USE & POLICY STUDIES – Health Technology Assessment Programs

PHP102

HEALTH TECHNOLOGY ASSESSMENT (HTA) ACTIVITY WORLDWIDE DURING 2012 AND 2013: MAIN TRENDS

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OBJECTIVES: HTA activity is constantly growing over time at a global level, a trend observed in both countries with well-consolidated HTA agencies, such as the UK, as well as in HTA-emerging countries, such as Brazil. The objective of this study was to explore trends in HTA activity during 2012 and 2013 worldwide, along with flagging newcomers. **METHODS:** Data were obtained from the Quintiles HTA Watch platform covering almost 100 HTA agencies in 32 countries. Published and ongoing HTA are captured in the database on a regular basis. Entries published from 1st of January 2012 till 31stof December 2013 were selected. The number of published reports by each agency and country/region was counted and were also stratified by therapeutic area and indication. Data from selected agencies based on their impact on reimbursement decisions were further explored. **RESULTS:** 3241 reports were found in total for all agencies monitored, out of which 1530 were published in 2012 and 1659 in 2013. HTA Activity in the UK is constantly rising as a total (214 reports published in 2012 and 254 in 2013 from NICE, SMC and AWMSG), as well as in the individual agencies (NICE experimented a 28% increase in the number of published reports). Increasing trends were also observed in France, Sweden, Canada and Australia, while Germany and Spain remained rather stable. Cancer, diabetes, digestive and musculoskeletal indications were the object of more evaluations in 2013 compared to 2012, while cardiovascular and central nervous systems indications experimented a decline in selected agencies. Newcomers include Colombia with IETS and more than 50 reports, and Spain with the Therapeutic Positioning Reports. **CONCLUSIONS:** Global statistics allowed us to describe trends in HTA activity that reinforce the conviction that evidence-based decisions are increasingly considered valuable/mandatory for reimbursement purposes and consequently, HTA activity is constantly in rise over the globe.

PHP103

NEED FOR SUBGROUP COST EFFECTIVENESS ANALYSES FOR HEALTH TECHNOLOGY ASSESSMENTS

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OBJECTIVES: Cost effectiveness analyses play a critical role in determining coverage of novel drugs and devices. Increasingly, payers are demanding subgroup analyses to determine indications which would be covered by the national health system or insurance agency. **METHODS:** To understand and review trends in the use of subgroup cost effectiveness analysis, we analyzed NICE HTAs for products approved between 2011-2012. Manufacturer submissions for CEA were compared to final review and decision by HTA agency. Analogs were identified and case studies were developed to further understand the use of subgroup analyses and cost effectiveness models. **RESULTS:** Decisions made by NICE in 2011-2012 show increasing trends towards the use of subgroup analysis for determining indications for coverage by national payer bodies. Between 2011-2012, 80% of the assessments included subgroup analyses. Approximately half of them included cost effectiveness analyses for various subgroups. Interestingly, the ICER values estimated by NICE for the same subgroups showed a large variation (1X-3X fold difference) compared to ICER values estimated by manufacturers. Selected case studies highlighted that for several products, NICE is recommending treatments only for subgroups whose ICER values are within the cost effectiveness threshold. **CONCLUSIONS:** New products need robust broader population and subgroup analyses for insurance coverage.

PHP104

THE HTA REGULATION ON THE BRAZILIAN HEALTH CARE SYSTEM AND ITS IMPACT ON FEDERAL SPENDING ON HEALTH TECHONOLOGIES SUPPLY THROUGH LAWSUITS

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OBJECTIVES: To analyze the impact of changes in Brazil's health care system legislation from 2009 (CITEC) and after 2011 (CONITEC) on lawsuits for health technologies supply and federal spending. **METHODS:** Survey of federal spending in health technologies supply through lawsuits. **RESULTS:** Lawsuits with the federal government as a defendant for health technologies supply started in 2002. Ten years later there were 3,205 individual lawsuits for which the government spent US$ 131.19 million. The number of lawsuits continued to grow, reaching 2,273 in 2008. Since 2009, the growth rate slowed, reaching the annual average of 1,579, showing a stabilizing trend over the last 3 years. Federal spending grew at an average rate of 150% per year: 221% per year until 2008, decelerating to 60% per year since 2008. The impact of these lawsuits creates a cumulative effect in federal spending because the technologies provided are for chronic diseases and continuous use. In 2012 and 2013, 5 medicines alone, all of them indicated for the treatment of rare diseases (e.g. idursulfase, galsulfase and eculizumab) represent more than 80% of the federal spending. **CONCLUSIONS:** Escalating lawsuits over the last decade in Brazil led to several initiatives that culminated with the publication of law 12,401/2011 that created the National Committee for Health Technology Incorporation to assist the Ministry of Health in the incorporation of new technologies in Brazil's health care system. The law established a deadline of 180 days for a decision to be made, based on scientific evidence of efficiency, accuracy, effectiveness and security, and on a comparative cost-benefit evaluation in relation to the technologies already incorporated. Decision must consider social participation, be clear and comprehensible. The deceleration in the annual rates of new lawsuits and the decrease in federal spending demonstrate that HTA applied to regulation may play a critical role in this context.

PHP105

THE ITALIAN MEDICINES AGENCY EXPERIENCE WITH HTA SCIENTIFIC ADVICE ACTIVITIES: A COMPREHENSIVE ANALYSIS OF THREE YEARS OF NATIONAL AND INTERNATIONAL ACTIVITIES

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OBJECTIVES: In the last years HTA-Scientific-Advice (HTA-SA) has been assuming a relevant role in decision process for assessment of new technologies for pricing and reimbursement in Europe. Since the beginning of the SA-initiatives, AIFA has been involved in multi-dimensional and multi-national advices: parallel-SA with European Medicines Agency (EMA), European-Network of HTA (EUnetHTA) Early-Dialogue, Tapestry Networks, National HTA-SA. The AIFA-HTA-SA procedure relates the assessment of manufacturer's briefing book; consultancies with clinical and HTA experts; face-to-face meeting with manufacturer and final report. This study aims at presenting an analysis of the HTA-SA programs over the last 3 years. **METHODS:** Comparative analysis of issues evaluated in different types of HTA-SA has been conducted, in terms of clinical development program (patients'characteristics and selection; choice of comparator; trial design; choice of endpoints, including patient-reported-outcomes, stratification/subgroups; safety), cost-effectiveness (modeling, resource utilization, utility values) and Place in Therapy (value proposition, added benefit). Finally, an analysis of concordance between manufacturers proposal and AIFA-advice has been performed. **RESULTS:** From 2011 to 2013, a total of 21 HTA-SAs were performed: 3 Tapestry-Networks-SAs; 3 National-HTA-SAs; 7 EUnetHTA-Early-Dialogues; 8 parallel-EMA-HTA-SAs. Nervous system and cancer diseases were the main therapeutic areas of requests, accounting for 57% of total HTA-SAs (respectively 6 products for each). The majority (52,4%) of HTA-SAs were requested in an early stage of clinical development (Phase I-II). The comparative analysis showed that clinical development items were systematically analysed among different types of HTA-SA, while the domains of cost-effectiveness and place in therapy were more relevant for EUnetHTA Early Dialogues and National HTA-SAs. The concordance analysis showed that target population, stratification/subgroups and choice of comparator(s) were critical issues. **CONCLUSIONS:** The HTA-SA-activities respond to the emerging need of early interaction among manufacturers, regulators and HTAs. Different types of HTA-SA reflect different institutional bodies approaches and peculiarities. The National-HTA-SA-program is expected to increase in the next future.